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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/729,343	10/16/1996	DOSUK D. LEE		3866

7590 04/23/2003

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EXAMINER	
WARE, TODD	

ART UNIT	PAPER NUMBER
1615	40

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/729,343	LEE ET AL.	
	Examiner	Art Unit	
	Todd D Ware	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-3,5,7,9-16,22,23,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,9-16,22,23,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *37* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of supplemental information disclosure statement filed 10-28-02 and request for extension of time (granted) and amendment both filed 12-23-02 is acknowledged. Claims 1, 3, 7, 9-16, and 25 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Simkiss (WO 94/02412; hereafter '412).**

3. '412 discloses injectable amorphous calcium phosphate that hardens to form bone in vivo. It is the position of the examiner that the instant ratio of calcium to phosphorous is disclosed in '412. '412 discloses hydroxyapatite as $Ca_5(OH)PO_4)_3$. The molar ratio of Ca to P is 1.67. '412 goes on to disclose negligible amounts of magnesium in the composition (as low as 0.001 moles for 1 mole calcium). Thus, the ratio of Ca to P is within the instant range. This also applies to tricalcium phosphate, $Ca_3(Po_4)_2$. Applicant has previously argued (in response to a 35 U.S.C. 103(a) rejection) that '412 doesn't disclose that the composition is resorbable. '412 discloses compositions comprising hydroxyapatite or tricalcium phosphate having magnesium and tricalcium phosphate is known to be resorbable. Furthermore, being that the Patent

Office is not capable of manufacture products and testing them, the burden is shifted to the applicant to demonstrate that that these compositions do not have the claimed functional limitations. This also applies to arguments regarding the endothermic reaction limitations. The instant claims (those dependant on and including claim 2) require an acidic second calcium phosphate. Dependant claims state that this is PCA calcium phosphate. Thus, '412 also anticipates these claims since this limitation only requires PCA calcium phosphate in the composition of the instant methods.

Response to Arguments

4. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant argues that the amorphous calcium phosphate and the instant poorly crystalline apatitic calcium phosphate differ in both chemical composition and degree of crystallinity and that since the instant claims require a poorly crystalline apatitic calcium phosphate, the instant invention is therefore allowable. However, the instant specification at page five, lines 20-27, page 7, line 14 through page 8, line 17, and page 14, line 12 through page 20, line 15, for example, discloses that an amorphous calcium phosphate is converted into the poorly crystalline apatitic calcium phosphate having the X-ray diffraction pattern of Figure 3C (broad peaks at 2θ values of 26°, 28.5°, 32°, and 33°). This is precisely what is taught in '412 (see Figure 1). Accordingly, Applicant's argument is not persuasive. Applicant also argues that the instant claims require *ex vivo* manufacture of a poorly crystalline apatitic calcium phosphate while '412 discloses an *in vivo* process. However, the instant claims do not provide such a requirement. Instead the instant claims state that a poorly crystalline

apatitic calcium phosphate is provided to an implant site. This does not differentiate between *ex vivo* and *in vivo* processes. Applicant then further argues that instant claim 25 requires hardening of the calcium phosphate at the implant site in an endothermic process and that the inclusion of an additional adhesive material to secure the prosthesis of '412 is evidence that the prosthesis of '412 is not capable of hardening on its own. This argument is not found persuasive. Page 6, lines 27-37 disclose that the implants of '412 are provided in mixtures of fast and slow-setting materials for dealing with the collapse of intervertebral discs. Accordingly, they have not yet set or hardened and this occurs *in vivo*.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simkiss (WO 94/02412; hereafter '412).

8. '412 teaches injectable amorphous calcium phosphate that hardens to form bone in vivo. It is the position of the examiner that the instant ratio of calcium to phosphorous is disclosed in '412. '412 discloses hydroxyapatite as $Ca_5(OH)PO_4)_3$. The molar ratio of Ca to P is 1.67. '412 goes on to disclose negligible amounts of magnesium in the composition (as low as 0.001 moles for 1 mole calcium). Thus, the ratio of Ca to P is within the instant range. This also applies to tricalcium phosphate, $Ca_3(Po_4)_2$. Applicant has previously argued (in response to a 35 U.S.C. 103(a) rejection) that '412 doesn't disclose that the composition is resorbable. '412 discloses compositions comprising hydroxyapatite or tricalcium phosphate having magnesium and tricalcium phosphate is known to be resorbable. Furthermore, being that the Patent Office is not capable of manufacture products and testing them, the burden is shifted to the applicant to demonstrate that that these compositions do not have the claimed functional limitations. This also applies to arguments regarding the endothermic reaction limitations. The instant claims (those dependant on and including claim 2) require an acidic second calcium phosphate. Dependant claims state that this is PCA calcium phosphate. Thus, '412 also anticipates these claims since this limitation only requires PCA calcium phosphate in the composition of the instant methods.

Response to Arguments

9. Applicant's arguments filed 12-23-02 have been fully considered but they are not persuasive. Applicant's arguments for the rejection under 35 U.S.C. 103(a) are the same as those for the rejection under 35 U.S.C. 102(b). Accordingly, the examiner's comments stated *supra*, paragraph 4, are again applicable here. As they are stated in paragraph 4, they are not repeated. As further applied to 35 U.S.C. 103(a), Applicant has not provided any data demonstrating that that these compositions do not have the claimed functional limitations and endothermic reaction limitations or the criticality of such limitations. Accordingly, this rejection is maintained.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-3, 5, 7, 9-16, 22-23, and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-27 of U.S. Patent No. 6,287,341. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the instant methods disclose the composition of '341.

12. Claims 1-3, 5, 7, 9-16, and 22-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-27 of U.S. Patent No. 6,287,341; claims 1-14 of U.S. Patent No. 6,214,368; claims 1-2 of U.S. Patent No. 6,132,463; claims 1-21 of U.S. Patent No. 6,027,742; claims 1-9 of U.S. Patent No. 6,331,312. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant methods are either the genus of a claimed species or disclose a claimed composition.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

tw
April 18, 2003